

Flash-KRAS - Retrospective observational study taking an inventory of the KRAS test in 2011 in patients with metastatic colorectal cancer having recently started a first-line treatment

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Last update : 10/19/2017 | Version : 1 | ID : 73327

General

Identification

Detailed name Retrospective observational study taking an inventory of the KRAS test in 2011 in patients with metastatic colorectal cancer having recently started a first-line treatment

Sign or acronym Flash-KRAS

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation CNIL n°1474442

General Aspects

Medical area Anatomy - Cytology
Biology
Cancer research

Pathology (details) Colorectal cancer

Health determinants Healthcare system and access to health care services

Keywords Flash-KRAS, Colorectal cancer

Scientific investigator(s) (Contact)

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Collaborations

Participation in projects, networks and consortia	No
Funding	
Funding status	Private
Details	Merck
Governance of the database	
Sponsor(s) or organisation(s) responsible	Merck
Organisation status	Private
Presence of scientific or steering committees	Yes
Labelling and database evaluation	Scientific committee
Additional contact	
Main features	
Type of database	
Type of database	Study databases
Database recruitment is carried out by an intermediary	A selection of health care professionals A selection of health institutions and services
Database recruitment is made on the basis of:	Another treatment or procedure
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	Retrospective, non-interventional pharmaco-epidemiological study. This study does not change the usual practices of the physician with respect to their patient.
Database objective	
Main objective	Evaluate the KRAS test prescription rate in patients starting a first-line treatment for metastatic colorectal cancer.
	Secondary objectives:

- Describe the potential reasons for not prescribing this test
- Describe and analyse the clinical characteristics of patients and treatments planned and received in first-line metastatic treatment
- Describe and analyse the time frame for obtaining the result of the KRAS test and the channel (who makes the request and when) and the therapeutic attitude adopted during this period
- Analyse the impact of the availability of the KRAS test and its result on the therapeutic choice of the physician
- Describe the technic used for the analysis, the type of mutation (if available) and the method for reporting the results to the clinicians (report of the results)

Inclusion criteria

Each participating centre had to select the exhaustiveness of the patients seen in consultation during the study period, meeting all of the following criteria:

- Patients aged 18 years or older,
- Patients with histologically proven metastatic colorectal cancer,
- Patients for whom a metastatic first-line treatment was initiated between 01/01/2011 and 27/03/2011,
- Patients seen in consultation during the official 2-week study selection period.

Population type

Age

- Adulthood (19 to 24 years)
- Adulthood (25 to 44 years)
- Adulthood (45 to 64 years)
- Elderly (65 to 79 years)
- Great age (80 years and more)

Population covered Sick population

Pathology II - Neoplasms

Gender Male
Woman

Geography area National

Detail of the geography area France

Data collection

Dates

Date of first collection (YYYY or YYYY-MM-DD) 28/03/2011

MM/YYYY)

Date of last collection (YYYY or MM/YYYY) 08/04/2011

Size of the database

Size of the database (number of individuals) [500-1000[individuals

Details of the number of individuals n=538 patients (160 centres)

Data

Database activity Data collection completed

Type of data collected
Clinical data
Declarative data
Biological data

Clinical data (detail) Direct physical measures

Details of collected clinical data History of early colorectal cancer; First line metastatic treatment; Prescription of KRAS biomarker genotyping; impact of the result on therapeutic management

Declarative data (detail) Paper self-questionnaire

Details of collected declarative data Demographic characteristics of the physician, data related to the medical practice, size of the town of the medical practice, physician's thesis year / Patient's demographics data

Biological data (detail) Waiting period for KRAS test result; genotyping report

Presence of a biobank No

Health parameters studied Health care consumption and services

Procedures

Data collection method Medical records of patients seen during the study period retrospectively and using a paper questionnaire. Anonymised copy of the molecular biology report

Participant monitoring No

Followed pathology

Links to administrative sources	No
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Promotion and access

Promotion

Link to the document	Lievre A et al. EJC Juin 2013.pdf
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Link to the document	Poster KRAS ESMO version finale.pdf
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Description	ESMO 2012
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Link to the document	poster Flash-KRAS JFHOD.pdf
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Description	JFHOD 2012
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Access

Presence of document that lists variables and coding procedures	No
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Terms of data access (charter for data provision, format of data, availability delay)	Access terms and conditions are being defined Contact: juliette.longin@merckgroup.com
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Access to aggregated data	Access on specific project only
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Access to individual data	No access
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